

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION**

STATE OF TEXAS and
LUBBOCK INDEPENDENT SCHOOL
DISTRICT,
Plaintiffs,

V.

XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services, et al.,
Defendants.

CIVIL ACTION No. 5:21-CV-300

**PLAINTIFFS' BRIEF IN SUPPORT OF THEIR
MOTION FOR SUMMARY JUDGMENT**

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TO THE HONORABLE JAMES WESLEY HENDRIX, U.S. DISTRICT JUDGE:

Plaintiffs, the State of Texas and Lubbock Independent School District, file this Brief in Support of Motion for Summary Judgment, and will respectfully show the Court as follows:

INTRODUCTION

The COVID-19 viral outbreak has been with us since around March 2020. As the Court knows from the parties' extensive prior briefing, on November 30, 2021, Defendants promulgated the Interim Final Rule at issue in this case.¹ The Interim Final Rule has an unprecedented permanent Vaccine Mandate and Mask Mandate.² It was implemented, supposedly, in response to expected increases in COVID cases, hospitalizations, and deaths due to the Delta variant at that time, and following the recommendation of the Centers for Disease Control ("CDC"). The CDC, unlike Defendants, is assumed to have expertise in public health and, of course, disease control.

On December 30, 2021, the Court granted Plaintiffs' request for a preliminary injunction, finding that Plaintiffs demonstrated a substantial likelihood of success on the merits on four of their claims, namely: (1) Defendants issued the Interim Final Rule without statutory authority; (2) Defendants failed to consult with required stakeholders in violation of the Head Start Act itself; (3) Defendants lacked "good cause" to skip notice-and-comment; and (4) the Interim Final Rule is arbitrary and capricious because it is unreasonably overbroad, imposes a one-size-fits-all approach with no end date, and constitutes a drastic change from Head Start's tradition of local flexibility.³

¹ Appx. 1-50 (86 Fed. Reg. 68,052 (Nov. 30, 2021) (November 30, 2021) (entitled "Vaccine and Mask Requirements To Mitigate the Spread of COVID-19 in Head Start Programs")).

² It amends 26 C.F.R. §§ 1302.47(b)(5)(vi) (Mask Mandate); .93(a)(1), (2) (Vaccine Mandate for staff and contractors); and .94(a) (Vaccine Mandate for volunteers)

³ Dkt. #42.

Since the Court issued the preliminary injunction, the Supreme Court has issued two opinions concerning the constitutionality of other COVID mandates. Both opinions strongly support the Court’s initial determination that Plaintiffs were likely to succeed on the merits—and the conclusion the Court should make here: the Interim Final Rule is unlawful and must be set aside.

STATEMENT OF FACTS

A. Head Start

Head Start is a federal grant program that provides funding to school districts, nonprofits, and other community educational providers. Head Start programs promote the school readiness of infants, toddlers, and preschool-aged children from low-income families.⁴

Head Start programs are available at no cost to children ages birth to 5 from low-income families.⁵ Families and children experiencing homelessness, and children in the foster care system are also eligible.⁶ Preschool students whose attendance is funded via Head Start grant funding are often in preschool classrooms with other students whose attendance is funded by either state funds, district funds, or parent tuition.⁷

Head Start programs deliver services through 1,600 agencies in local communities, and provide services to more than a million children every year, in every U.S. state and territory.⁸

The purpose of Head Start is to “promote the school readiness of low-income children by enhancing their cognitive, social, and emotional development—(1) in a learning environment that supports children’s growth in language, literacy, mathematics, science, social and emotional

⁴ Head Start Programs, Office of Head Start (Nov. 3, 2020), <https://www.acf.hhs.gov/ohs/about/head-start> (last visited April 14, 2022).

⁵ *Id.*

⁶ *Id.*

⁷ See Appx. 52.

⁸ *Supra*, n.4.

functioning, creative arts, physical skills, and approaches to learning; and (2) through the provision to low-income children and their families of health, educational, nutritional, social, and other services that are determined, based on family needs assessments, to be necessary.”⁹

The Office of Head Start provides grants to Head Start agencies in Texas (including grants to agencies of the State of Texas, such as Texas Tech University) and throughout the country. Head Start programs are operated by several types of entities, including independent school districts. Staff employed by Head Start programs are not federal employees.

According to the United States Department of Health and Human Services’ Tracking Accountability in Government Grants System website, HHS awarded a total of \$842,280,184 in grants to Texas Head Start programs in fiscal year 2021.¹⁰

B. Reaction to COVID-19

As explained in Office of Head Start guidance (Log No. ACF-PI-HS-21-04, Issuance Date: 05/20/2021),¹¹ beginning in Spring 2020, the Office of Head Start allowed virtual and remote services for children as “an interim strategy in the presence of an emergency or disaster.”¹² “Virtual” means “services for children provided through technology,” and “remote” means “services provided via the delivery of supports and resources, such as educational materials or food boxes.”¹³ Nonetheless, “[a]lmost one third of children served in Head Start programs before the pandemic — approximately 250,000 — have not received any services to date.”¹⁴

⁹ 42 U.S.C. § 9831.

¹⁰ *See* Appx. 56–89.

¹¹ Appx. 91–92., Appx. 97

¹² *Id.* at 91.

¹³ *Id.* at 90.

¹⁴ *Id.* at 92.

As this Court noted in its Order granting Plaintiffs' request for a preliminary injunction,¹⁵ Head Start has a documented history of success from flexible practices depending on local needs.¹⁶ In its May 2021 guidance, the agency recognized that “[t]o date, OHS provided needed flexibilities and guidance that allowed programs to adapt services *based on the changing health conditions in their communities.*”¹⁷ As a result, some Head Start programs offered virtual and remote services, but “[m]any programs continued to provide in-person services for children and families throughout the COVID-19 pandemic.”¹⁸ The guidance instructed its in-person programs “to continue serving children in person, *as local health conditions allow*” and encouraged programs to “move to in-person services, *as local health conditions allow.*”¹⁹ During the pandemic, local programs decided to close, operate remotely or hybrid, or offer fully in-person services, depending on their circumstances.²⁰ In September 2021, 73% of centers were open for in-person services, 14% operated in a hybrid model, and 4% were virtual.²¹ Only 2% were entirely closed due to COVID-19.²²

A December 2020 report from the CDC studied the implementation of mitigation strategies in early childhood education settings.²³ The CDC reported that, while “[m]ost states required all schools (K-12) to close or transition to virtual learning,” the Office of Head Start “gave its local programs that remained open the flexibility to use CARES Act funds to implement CDC-

¹⁵ Dkt.# 42 at 35–36.

¹⁶ Appx. 93.; Appx. 100–104.

¹⁷ Appx. 91 (emphasis added).

¹⁸ *Id.*

¹⁹ *Id.* (emphasis added).

²⁰ Appx. 7 (86 Fed. Reg. at 68,058).

²¹ *Id.*

²² *Id.*

²³ Appx.100–104.

recommended guidance.”²⁴ The result? “Head Start programs successfully implemented CDC-recommended mitigation strategies and supported other practices that helped to prevent SARS-CoV-2 transmission among children and staff members.”²⁵ The CDC stressed that the flexibility provided to local Head Start programs was key to the success: “Since the COVID-19 pandemic started, Head Start and Early Head Start programs successfully implemented CDC-recommended mitigation strategies and applied other innovative approaches to limit SARS-CoV-2 transmission among children, teachers, and other staff members *by allowing maximum program flexibility* and allocating financial and human resources.”²⁶ The report concludes that “[c]hild care settings should implement concurrent preventive measures and *adjust these strategies based on community transmission data.*”²⁷

C. The Head Start Interim Final Rule, the Vaccine Mandate, and the Mask Mandate

On November 30, 2021, Defendants issued the Interim Final Rule with its Vaccine Mandate and Mask Mandate.²⁸ Defendants thereby abandoned their previous flexible approach, instead adopting what this Court has aptly described as “a one-size-fits-all approach with no end date.”²⁹

Vaccine Mandate for staff and Contractors. The Interim Final Rule adds paragraphs (a)(1) and (2) to 45 C.F.R. § 1302.93:

- (1) All staff, and those contractors whose activities involve contact with or providing direct services to children and families, must be fully vaccinated for COVID-19, other than those employees:
 - (i) For whom a vaccine is medically contraindicated;

²⁴ Appx.100.

²⁵ *Id.*

²⁶ Appx. 102. (emphasis added).

²⁷ Appx. 103.

²⁸ Appx. 1 (86 Fed. Reg. 68,052); *see also* Plaintiff’s Complaint at 10–16, ¶¶ 39–53 (describing the Vaccine Mandate and the Mask Mandate).

²⁹ Dkt.#42 at 33.

- (ii) For whom medical necessity requires a delay in vaccination; or
- (iii) Who are legally entitled to an accommodation with regard to the COVID-19 vaccination requirements based on an applicable Federal law.

(2) Those granted an accommodation outlined in paragraph (a)(1) of this section must undergo SARS-COV-2 testing for current infection at least weekly with those who have negative test results to remain in the classroom or working directly with children. Those with positive test results must be immediately excluded from the facility, so they are away from children and staff until they are determined to no longer be infectious.

Appx. 50 (86 Fed. Reg. at 68,101).

The new paragraphs require staff and contractors to be vaccinated, and to get tested weekly if granted an accommodation against being vaccinated. No such requirement existed in the prior version.

Vaccine Mandate for Volunteers. The Interim Final Rule revises paragraph (a) of 45 C.F.R. § 1302.94 to read as follows:

- (a) A program must ensure volunteers have been screened for appropriate communicable diseases in accordance with state, tribal or local laws. In the absence of state, tribal, or local law, the Health Services Advisory Committee must be consulted regarding the need for such screenings.
- (1) All volunteers in classrooms or working directly with children other than their own must be fully vaccinated for COVID-19, other than those volunteers:
 - (i) For whom a vaccine is medically contraindicated;
 - (ii) For whom medical necessity requires a delay in vaccination; or
 - (iii) Who are legally entitled to an accommodation with regard to the COVID-19 vaccination requirements based on an applicable Federal law.
- (2) Those granted an accommodation outlined in paragraph (a)(1) of this section must undergo SARS-CoV-2 testing for current infection at least weekly with those who have negative test results to remain in the classroom or work directly with children. Those with positive test results must be immediately excluded

from the facility, so they are away from children and staff until they are determined to no longer be infectious.

Appx. 50 (86 Fed. Reg. at 68,101).

The new paragraphs require volunteers to be vaccinated, and to get tested weekly if granted an accommodation against being vaccinated. No such requirement existed in the prior version.

Mask Mandate. The Interim Final Rule adds paragraph (b)(5)(vi) to 45 C.F.R. § 1302.47(b)(5):

- (vi) Masking, using masks recommended by CDC, for all individuals 2 years of age or older when there are two or more individuals in a vehicle owned, leased, or arranged by the Head Start program; indoors in a setting when Head Start services are provided; and for those not fully vaccinated, outdoors in crowded settings or during activities that involve sustained close contact with other people, except:
 - (A) Children or adults when they are either eating or drinking;
 - (B) Children when they are napping;
 - (C) When a person cannot wear a mask, or cannot safely wear a mask, because of a disability as defined by the Americans with Disabilities Act; or
 - (D) When a child's health care provider advises an alternative face covering to accommodate the child's special health care needs.

Appx. 50 (86 Fed. Reg. at 68,101).

The new paragraph requires masking. No such requirement existed in the prior version.

The Vaccine Mandate forces local Head Start programs, including the programs operated by Texas Tech University and Lubbock Independent School District ("LISD"), to choose between ignoring the Mandate and risking the cancellation of grant funding,³⁰ cancelling the program and

³⁰ 45 C.F.R. § 1304.5. Funding can be cut off without notice "if there is an emergency situation, such as a serious risk [of] harm to staff or participants' health and safety." 45 C.F.R. § 1304.4(a). Presumably, Defendants view exposure to unvaccinated employees and volunteers, and exposure

depriving children of Head Start services, or forcing their staff, contractors, and volunteers to comply with an illegal federal mandate that violates their constitutional rights, while dealing with the inevitable fallout from the resulting resignations that will damage the program.

The Mask Mandate likewise forces Head Start programs to make similar choices. And it also forces Texans with children in Head Start to choose between complying with the illegal mandate and allowing staff to force their children to wear masks, or withdrawing their children from the program.

PROCEDURAL HISTORY

On December 10, 2021, Plaintiffs filed this lawsuit. Sometime later, Defendants compiled the administrative record and filed it on December 27.³¹ On December 31, the Court granted Plaintiffs' request for preliminary injunction but limited the ruling "within the State of Texas."³² Thus, the Vaccine Mandate and Mask Mandate have not been in effect in Texas during 2022.

Defendants filed a motion to dismiss, or in the alternative, a motion for summary judgment.³³ Plaintiffs' response is due on May 4.³⁴

LEGAL DEVELOPMENTS SINCE DECEMBER 31

A district court in Louisiana also issued a preliminary injunction against the Interim Final Rule in twenty-four plaintiff states on January 1. *Louisiana v. Becerra*, No. 3:21-CV-04370, 2022 WL 16571 (W.D. La. 2022). But a district court in Michigan denied a request by four Michigan school

to unmasked children and adults, to such a serious risk of harm, and that Head Start programs that fail to comply with the Mandates are subject to loss of funding without notice.

³¹ Dkt. #21 at 3 ("The agency expects that the administrative record will comprise over 100 documents"—indicating that it did not yet exist on December 21, the date of the filing of Dkt. # 21); Appx. 94-99 (table of contents of administrative record, filed on December 27, 2021).

³² Dkt. #42 at 56.

³³ Dkt. ##48, 49, 50.

³⁴ See Dkt. #53.

districts for a similar preliminary injunction on March 4. *Livingston Educ. Serv. Agency v. Becerra*, No. 22-CV-10127, 2022 WL 660793 (E.D. Mich. Mar. 4, 2022).

On January 13, the Supreme Court stayed preliminary injunctions issued by two district courts against a rule issued by the Secretary of Health and Human Services announcing that, in order to receive Medicare and Medicaid funding, participating facilities must ensure their staff—unless exempt for medical or religious reasons —are vaccinated against COVID-19 (“the CMS Mandate”). *Biden v. Missouri*, 142 S. Ct. 647, 650 (2022). (The *Livingston Educ. Serv. Agency* court stated that this Court’s and the Louisiana Court’s preliminary injunctions “are not binding here and were issued before the Supreme Court’s decision in *Biden v. Missouri*, which upheld a similar vaccination requirement.” *Livingston Educ. Serv. Agency* at *5 n.3. As further discussed below, Plaintiffs disagree with that analysis. *Biden v. Missouri* did not deal with “a similar vaccination requirement,” and the opinion in fact supports this Court’s preliminary injunction in several ways.

The same day as the Court stayed a preliminary injunction against the CMS Mandate, the Supreme Court also reversed the Sixth Circuit and stayed the Occupational Safety and Health Administration’s rule mandating that employers with at least 100 employees require that their employees either be vaccinated or obtain a medical test each week at their expense and on their time and wear a mask each day (“the OSHA Mandate”). *Nat’l Fed’n of Indep. Bus. v. Dep’t of Labor, Occupational Safety & Health Admin.* (“*NFIB*”), 142 S. Ct. 661, 662 (2022).

STATEMENT OF THE ISSUES

1. Whether the Interim Final Rule violates the Administrative Procedure Act because it is “in excess of statutory jurisdiction, authority, or limitations, or short of statutory right,” or violates

the Major Questions Doctrine, or both, and therefore must be “held unlawful and set aside” under 5 U.S.C. § 706(2)(C).

2. Whether the Interim Final Rule is simply an extension of preexisting longstanding regulations, and therefore justified under *Biden v. Missouri*’s new recognition that “the exercise of authorities that agency has long been recognized to have” are difficult to challenge. *Id.* at 644.

3. Whether the Interim Final Rule was adopted in violation of (1) the Head Start Act itself, 42 U.S.C. § 96316a(a)(2), the notice-and-comment requirement (5 U.S.C. § 553(b), (c), (d), (3) the Congressional Review Act, or (4) the Treasury and General Governmental Appropriations Act of 1999, therefore must be set aside because it was undertaken “without observance of procedure required by law” under 5 U.S.C. § 706(2)(D).

4. Whether the Interim Final Rule violates the Administrative Procedure Act because it is “arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law,” and therefore must be “held unlawful and set aside” under 5 U.S.C. § 706(2)(A).

5. Whether the Interim Final Rule is an unconstitutional exercise of the Spending Power.

6. Whether the Interim Final Rule violates the constitutional Anti-Commandeering Principle.

7. Whether the Interim Final Rule violates the Tenth Amendment.

STANDARD OF REVIEW

A “court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). The mere existence of some factual dispute will not defeat summary judgment unless that factual dispute is material to an issue affecting the outcome of the case. *Anderson v. Liberty Lobby*, 477 U.S. 242, 247–49 (1986). The

movant “must demonstrate the absence of a genuine issue of material fact,” but does not have “to negate the elements of the nonmovant’s case.” *Id.*; *Boudreax v. Swift Transp. Co.*, 402 F.3d 536, 540 (5th Cir. 2005).

It is a foundational principle of administrative law that judicial review of agency action is limited to the grounds that the agency invoked when it took the action. *Dep’t of Homeland Sec. v. Regents of the Univ. of California*, 140 S. Ct. 1891, 1907 (2020). It is well-established that an agency’s action must be upheld, if at all, on the basis articulated by the agency itself. *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983). “[A] reviewing court, in dealing with a determination or judgment which an administrative agency alone is authorized to make, must judge the propriety of such action solely by the grounds invoked by the agency” *SEC v. Chenery* (“*Chenery II*”), 332 U.S. 194, 196 (1947) .

ARGUMENT & AUTHORITIES

The Court must set aside the Interim Final Rule and permanently enjoin its enforcement because violates statutory provisions that unambiguously delineate Defendants’ rulemaking authority and the procedural requirements that govern that rulemaking. It violates constitutional provisions as well.

A. The Interim Final Rule lacks statutory authority.

“Administrative agencies are creatures of statute. They accordingly possess only the authority that Congress has provided.” *NFIB*, 142 S. Ct. at 665. “The challenges posed by a global pandemic do not allow a federal agency to exercise power that Congress has not conferred on it.” *Biden v. Missouri*, 142 S. Ct. at 654. “[O]ur system does not permit agencies to act unlawfully even in pursuit of desirable ends.” *Ala. Ass’n of Realtors v. Dep’t of Health & Human Servs.*, 141 S. Ct. 2485, 2490 (2021).

The Interim Final Rule was issued by the Office of Head Start, the Administration for Children and Families, and HHS. Appx. 1 (86 Fed. Reg. at 68,052). The Office of Head Start is within the Office of Early Child Development, which is in the Administration for Children and Families, which is in HHS. Those entities are federal agencies, or parts of federal agencies, subject to the requirements of the Administrative Procedure Act.

Under the APA, courts must “hold unlawful and set aside agency action” that is “not in accordance with law” or “in excess of statutory ... authority[] or limitations, or short of statutory right.” 5 U.S.C. § 706(2)(A), (C).

1. **42 U.S.C. § 9836a(a)(1)(C), (D), and (E) do not plainly authorize Defendants to mandate vaccinations or masks. Therefore, the Interim Final Rule violates the Major Questions Doctrine.**

An agency may implement a rule only when Congress authorizes it to do so. “[A]n agency literally has no power to act ... unless and until Congress confers power upon it.” *La. Pub. Serv. Comm’n v. FCC*, 476 U.S. 355, 374 (1986).

Defendants cite 42 U.S.C. § 9836a(a)(1)(C), (D), and (E) as the authority for issuing the Vaccine Mandate and the Mask Mandate. Appx. 2 (86 Fed. Reg. at 68,053). Those subsections provide: “The Secretary shall modify, as necessary, *program performance standards* by regulation applicable to Head Start agencies and programs under this subchapter, including (C) administrative and financial management standards; (D) standards relating to the condition and location of facilities (including indoor air quality assessment standards, where appropriate) ... [and] (E) such other standards as the Secretary finds to be appropriate” (emphasis added).

Section 9836a authorizes the Secretary to regulate “program performance standards,” it does not authorize defendants to mandate an invasive, permanent medical treatment for or mask

mandates for Head Start program children, staff, contractors, and volunteers. Notably, it does not mention vaccinations or masking requirements at all.

Moreover, as the Court has previously recognized, the Vaccine Mandate and Mask Mandate are “two unprecedented conditions on funding for Head Start programs.”³⁵ And as the Supreme Court recognized in *NFIB*, requiring vaccines “is a significant encroachment into the lives—and health—of vast number pf employees.” *NFIB*, 142 S. Ct. at 665. Therefore, Congress must “speak clearly” to authorize the exercise of such powers, and the question is whether 42 U.S.C. § 9836a(a)(1)(C), (D), and (E) “plainly authorize the Secretary’s mandate.” *Id.* Just as in *NFIB*, it does not.

The Interim Final Rule is based on a public health threat, but none of these subsections empower Defendants to set broad health safety measures. *See NFIB*, 142 S. Ct. at 665 (“The Act empowers the Secretary to set *workplace* safety standards, not broad public health measures.”) (emphasis in original). Although Defendants are empowered to “modify, as necessary, program performance standards by regulation applicable to Head Start agencies and programs under this subchapter, including (C) administrative and financial management standards; (D) standards relating to the condition and location of facilities (including indoor air quality assessment standards, where appropriate) … [and] (E) such other standards as the Secretary finds to be appropriate,” 42 U.S.C. §9831a(a)(1), those statutes have “not given [Defendants] the power to regulate public health more broadly.” *NFIB*, 142 S. Ct. at 666. Just as “OSHA’s indiscriminate approach fail[ed] to account for [the] crucial distinction—between occupation risk and risk more generally—and accordingly [the OSHA Mandate] takes on the character of a general public health

³⁵ Dkt.#42 at 1

measure rather than an occupational safety or health standard,” *id.*, Defendants’ Interim Final Rule also fails to distinguish between the limited power to modify certain performance standards with the power to issue general health measures. Just like OSHA cannot “regulate the hazards of daily life” or combat “universal risk” or “day-to-day dangers that all face from crime, air pollution, or any number of communicable diseases,” *NFIB*, 142 S. Ct. at 665, Defendants do not have the power to do so.

Congress knows how to plainly authorize immunizations. *See* 22 U.S.C § 2504(f) (mandating that Peace Corps volunteers receive immunizations); 8 U.S.C. § 1182(a)(1)(A)(ii) (providing that aliens must “present documentation of having received vaccination against vaccine-preventable diseases, which shall include at least the following diseases: mumps, measles, rubella, polio, tetanus and diphtheria toxoids, pertussis, influenza type B and hepatitis B, and any other vaccinations against vaccine-preventable diseases recommended by the Advisory Committee for Immunization Practices” or they are ineligible for visas or admission. That Congress did not do so here further indicates that it did not confer this authority on Defendants.

The *NFIB* court applied the Major Questions Doctrine to the OSHA Mandate and found it wanting. The Interim Final Rule should likewise be set aside as it violates the Major Questions Doctrine.

2. The Vaccine Mandate and Mask Mandate are not “program performance standards” and are neither administrative standards, standards relating to the condition and location of facilities, or such other standards as the Secretary finds to be appropriate.

Unlike *NFIB*, *Biden v. Missouri* does not address the Major Questions Doctrine; the Court relies instead on what could be characterized as an adverse possession of power theory. *See* Part B, *supra*. Here, even if the Major Questions Doctrine does not apply, the Interim Final Rule would

still be outside Defendants' asserted statutory authority—42 U.S.C. § 9836a(a)(1)(C), (D), and (E).

Section 9836a authorizes Defendants to “modify, as necessary, program performance standards.” Defendants claim that the Vaccine Mandate and the Mask Mandate are simply “modifications” of pre-existing “program performance standards.” Defendants are wrong on both counts.

First, the Mandates do not merely “modify” pre-existing performance standards. As the Court noted in its order granting preliminary injunctive relief:

At the outset, Congress appears to have limited the scope of the Secretary’s power. The Secretary may only “modify” program performance standards. [42 U.S.C. § 9836a.] This is not a broad grant of rulemaking power like defendants suggest. Rather, by enabling the Secretary to only “modify” program performance standards, Congress conferred modest authority. To “modify” means to “make somewhat different; to make small changes to (something) by way of improvement, suitability, or effectiveness . . . [t]o make more moderate or less sweeping; to reduce in degree or extent; to limit, qualify, or moderate.” *Modify*, Black’s Law Dictionary (11th ed. 2019); *see also MCI Telecomm. Corp. v. Am. Tel. & Tel. Co.*, 512 U.S. 218, 225 (1994) (“Virtually every dictionary we are aware of says that ‘to modify’ means to change moderately or in minor fashion”).

With the power to “modify,” the Secretary may only make moderate changes to Head Start performance standards. Against this backdrop, the Court finds that enacting unprecedented mask and vaccine mandates are not moderate changes to the specific standards defendants try to leverage.

Dkt. #42 at 13. Because the mandates are not “modifications” of “program performance standards,” Defendants lack authority to issue them under this statute.

Second, the Mandates are not “program performance standards.” “Performance standards” is not defined in § 9836a. But “performance standards” is a plain and unambiguous term, so the ordinary definition applies. *Carcieri v. Salazar*, 555 U.S. 379, 387 (2009) (“This case requires us to apply settled principles of statutory construction under which we must first determine whether

the statutory text is plain and unambiguous. If it is, we must apply the according to its terms.”)
(cleaned up).

Ordinarily, a “performance standard” is a threshold criterion to measure quality or acceptability of a required or contractual action.³⁶ But this is not what the mandates do. As the Court held in its Order granting Plaintiffs’ Motion for Preliminary Injunction, the mandates are prerequisites to the provision of service. Dkt.#42 at 16–17.

Generally, “performance standards” are criteria that measure the quality of Head Start programs. See Standard, Black’s Law Dictionary (11th ed. 2019) (“A criterion for measuring acceptability, quality, or accuracy”). Here, “quality” corresponds to Head Start programs’ ability to achieve their purpose. Under the Act, that purpose is to “promote the school readiness of low-income children by enhancing their cognitive, social, and emotional development” through providing a host of services—including health services to the children and their families. 42 U.S.C. § 9831(2).

The vaccine mandate does not measure staff and volunteers’ ability to enhance children’s development; it determines whether they will be kept on, hired, or fired in the first place. Likewise, requiring all children ages two to five to wear masks is not a benchmark that measures the quality of services provided, health-related or not. Rather, it defines whether children may receive Head Start services at all. These mandates are prerequisites to performance, not performance standards themselves. Both set conditions for participation and employment. They do not

³⁶ See STANDARD, Black’s Law Dictionary (11th ed. 2019) (“2. A criterion for measuring acceptability, quality, or accuracy <the attorney was making a nice living — even by New York standards>. — standard, *adj.*.”); PERFORMANCE, Black’s Law Dictionary (11th ed. 2019) (“performance *n.* (16c) 1. The successful completion of a contractual duty”); *see also* Developing Performance Standards (opm.gov) <https://www.opm.gov/policy-data-oversight/performance-management/performance-management-cycle/planning/developing-performance-standards/> (“A performance standard is a management-approved expression of the performance threshold(s), requirement(s), or expectation(s) that must be met to be appraised at a particular level of performance.”); *see, e.g.*, *Salmon v. Soc. Sec. Admin.*, 663 F.3d 1378, 1383 (Fed. Cir. 2011) (“Performance standard means the management-approved expression of the performance threshold(s), requirement(s), or expectation(s) that must be met to be appraised at a particular level of performance[.]”); *Wilson v. Dep’t of Health & Hum. Servs.*, 770 F.2d 1048, 1053 (Fed. Cir. 1985) (“A performance standard for this critical element defines minimally acceptable performance for this activity[.]”).

measure quality. Defendants' construction of their cited authorities is impermissible for this fundamental reason.

Dkt. #42 at 16-17.

Moreover, nowhere in the Interim Final Rule is there any attempt to explain, or even mention, how the amendments to 45 C.F.R. §§ 1302.047 (Mask Mandate), .093 (Vaccine Mandate for staff), or .094 (Vaccine Mandate for volunteers) might be justified as a modification of a program performance standard, or (with one exception discussed below) how they could be program performance standards in the first place.

Third, even if the Mandates were modifications of pre-existing program performance standards, the Vaccine Mandate and Mask Mandate are not administrative standards, standards relating to the condition and location of facilities, or such other standards as the Secretary finds to be appropriate, and so are not authorized by the authority of 42 U.S.C. § 9836a(a)(1)(C) ("administrative and financial management standards"), (D) ("standards related to the condition and location of facilities ... including regulations that require that the facilities ... (i) shall meet or exceed State and local requirements concerning licensing for such facilities; and (ii) shall be accessible by State and local authorities for purposes of monitoring and ensuring compliance, unless State or local laws prohibit such access"), or (E) ("such other standard as the Secretary finds to be appropriate").

The Interim Final Rule contains no argument or explanation how the Mandates could be an administrative or financial management standard, authorized by 42 U.S.C. § 9836a(a)(1)(C).

Defendants concede the mandates are not financial management standards.³⁷ The mandates cannot be authorized as an administrative standard, because, as the Court has held:

[T]he Secretary may not impose these mandates by purporting to modify administrative standards. “Administrative” is not defined by the statute but generally refers to “of or relating to administration,” and “administration” is the “performance of executive duties: management.” *Administrative*, Merriam-Webster’s Collegiate Dictionary (11th ed. 2014); *Administration*, Merriam-Webster’s Collegiate Dictionary (11th ed. 2014). By placing the vaccine mandate in the “Human Resources Management” section of the regulations, defendants seem to interpret “administrative” standards to include requiring its employees to undergo a mandatory offsite medical procedure or be fired if they are not granted an exemption. *See* 86 Fed. Reg. at 68,060 (noting that the Rule adds four new provisions to “part 1302, subpart I—Human Resources Management” in 45 C.F.R. §§ 1302.93–94). Such a requirement would not typically be characterized as relating to executive duties or management. If it were, there would be no limit to the scope of administrative standards. Defendants could then impose any requirement on Head Start staff, contractors, volunteers, and children by modifying “administrative standards.”

Rather, the scope of “administrative standards” is informed by the term to which it is joined: “financial management standards.” § 9836a(a)(1)(C). Congress grouped the two together—not only in the same list, but in the same subsection. *See id.* Statutory terms are often known by the “company they keep.” *See Lagos v. United States*, 138 S. Ct. 1684, 1688–89 (2018) (Breyer, J., writing for a unanimous Court) (citing *Yates v. United States*, 574 U.S. 528, 542 (2015)) (finding “both the presence of company that suggests limitation and the absence of company that suggests breadth”). The agency concedes that the company “administrative” keeps—“financial management”—obviously cannot authorize the Rule. [Dkt. #41] at 48. Read together, the term “financial management standards” “suggests limitation” on the scope of the term “administrative standards.” *Id.* The terms appear to contemplate management standards like those found in 45 C.F.R. § 1302.101(a)(1)—requiring programs to use effective “fiscal[] and human resource management structure[s]”—not mandatory masking and vaccine requirements. Given that the masking and vaccine mandates aim to protect children’s health, it defies logic to assert that such standards would be characterized as administrative or financial.

Dot. 42 at 13–15.

Furthermore, the federal government failed to justify the CMS Mandate as an “administrative” measure:

³⁷ Appx. 152; *see also* Dkt. #42 at 13.

The Government begins by invoking two statutory provisions that generally grant CMS authority to promulgate rules to implement Medicare and Medicaid. The first authorizes CMS to “publish such rules and regulations … as may be necessary to the efficient administration of the [agency’s] functions.” 42 U. S. C. § 1302(a). The second authorizes CMS to “prescribe such regulations as may be necessary to carry out the administration of the insurance programs” under the Medicare Act. § 1395hh(a)(1).

Biden v. Missouri, 142 S. Ct. at 655 (Thomas, J. dissenting). But “[a]t oral argument, the Government largely conceded that § 1302(a) and § 1395hh(a)(1) alone do not authorize the omnibus rule.” *Id.* at 656. And “the Court [did] not rely on the Government’s proffered statutory provisions.” *Id.* at 658. The Court upheld the CMS Mandate largely because there were longstanding regulations of healthcare worker behavior in the interest of patient safety. See Part B, *supra*. Thus, even the opinion that upheld a vaccine mandate did not uphold it as an “administrative measure.”

Defendants attempt to justify the Mandates under subsection (D) also fails. The Interim Final Rule contains one sentence which is seemingly intended to explain how the Mandates are a “standard relating to the condition … of facilities”: “The Secretary finds it necessary and appropriate to set health and safety standards for the condition of Head Start facilities that ensure the reduction in transmission of the SARS-CoV-2 and to avoid severe illness, hospitalization, and death among program participants.” Appx. 3 (86 Fed. Reg. at 68,054). But by its terms, this sentence refers to “health and safety standards,” not to a “standard relating to the condition … of facilities.” Moreover, health and safety requirements for employees, volunteers, and children simply are not standards about the condition of facilities. They are standards about the condition of people.

Defendants' reliance on this subsection for their authority to promulgate these mandates is untenable. As this Court has held, "the plain language of subsection (D) suggests that the Secretary may *not* impose the mask and vaccine mandates." Dkt. #42 at 15 (emphasis added).:

Subsection (D) enables the Secretary to modify "standards relating to the condition and location of facilities (including indoor air quality assessment standards, where appropriate)." § 9836a(a)(1)(D). "Facility" is defined as "a structure, such as a building or modular unit, appropriate for use in carrying out a Head Start program and used primarily to provide Head Start services." 45 C.F.R. § 1305.2 (2021). Subsection (D) specifies that the condition and location of facilities must "meet or exceed State and local requirements concerning licensing for such facilities" and "be accessible by State and local authorities for purposes of monitoring and ensuring compliance." § 9836a(a)(1)(D)(i) & (ii). The "condition" of facilities—as the references to "indoor air quality assessment standards," licensing, and accessibility make clear—relate to physical conditions of buildings and equipment—not conditions on children's participation and adults' employment or volunteer eligibility. Mandating facility standards is a far cry from mandating a medical procedure for all staff under the threat of termination and what participants must wear. *See Texas v. Becerra*, 2021 WL 5964687, at *5 (N.D. Tex. Dec. 15, 2021) (Kacsmaryk, J.) ("Mandating facility standards is drastically different from mandating who a healthcare provider hires or fires.").

Dkt. #42 at 15–16.

The Interim Final Rule also does not explain or even mention how the Mandates might be justified as an "other standard[] as the Secretary finds to be appropriate" under subsection (a)(1)(E). If subsection (a)(1)(E) allowed Defendants to adopt any regulation they wanted, it would violate the nondelegation doctrine. "The nondelegation doctrine bars Congress from transferring its legislative power to another branch of Government." *Gundy v. United States*, 139 S. Ct. 2116, 2121 (2019). But statutory delegations are permissible if "Congress has supplied an intelligible principle to guide the delegee's use of discretion." *Id.* at 2123.

But subsection (a)(1)(E) does not grant unfettered authority. The rule of ejusdem generis limits general terms which follow specific ones to matters similar to those specified. *Gooch v. United*

States, 297 U.S. 124, 128 (1936). Thus, “other such standards” in subsection (a)(1)(E) are limited to standards similar to those listed in subsections (a)(1)(A)–(D). If this subsection is read to authorize mask and vaccine mandates, then there is no limit to the Secretary’s authority to promulgate regulatory measures in the name of “health and safety standards.” *See* Dkt. #42 at 17.

Moreover, last year, the Supreme Court invalidated the CDC’s promulgation of a COVID-19-related regulation under the agency’s seemingly broad authority “to make and enforce such regulations as . . . are necessary to prevent the introduction, transmission, or spread of communicable diseases”—a sweeping “catch-all” provision similar to the statute at issue here. *Alabama Ass’n of Realtors v. Dep’t of Health & Hum Servs.*, 141 S. Ct. 2485, 2489 (2021). The Supreme Court determined that the “sheer scope of the CDC’s claimed authority [under the catch-all provision] would counsel against the Government’s interpretation. We expect Congress to speak clearly when authorizing an agency to exercise powers of vast economic and political significance.” *Id.* at 2489. Here, too, the Court should find that Defendants’ “claim to expansive authority based on generalized and catch-all language” is not only insufficient to demonstrate delegated authority but emphasizes Defendants’ *lack* of authority. *See* Dkt. #42 at 18.

If the CDC—which (unlike Defendants) has authority to “make and enforce such regulations . . . necessary to prevent the introduction, transmission, or spread of communicable diseases,” *Alabama Ass’n of Realtors*, 141 S. Ct. at 2487 (quoting 42 U.S.C. § 264(a))—cannot issue an eviction moratorium to control the spread of communicable diseases, *id.* at 2489, then Defendants, lacking similar authority, cannot regulate the medical treatment of staff or other individuals by mandating vaccinations.

If Defendants' logic is that the Vaccine Mandate and the Mask Mandate can be implemented because the Secretary can implement "other standards as the Secretary finds to be appropriate" under subsection (a)(1)(E), then the same logic would support the implementation of any "performance standard" Defendants might wish to impose on Head Start staff and children, such as mandating flu vaccines or weekly RSV testing. This would be limitless, unguided authority in violation of the non-delegation doctrine.

Fourth, although Defendants are statutorily authorized to "modify, as necessary, program performance ... including ... performance standards with respect to services required to be provided, including health ... services," 42 U.S.C. § a(a)(1)(A), the Interim Final Rule is not based on that statutory authorization. The Court explained the significance of this in its Order granting preliminary relief, which Plaintiffs again adopt:

[T]here was never any doubt that the Secretary could establish certain performance standards related to "health services." Subsection (A) of program performance standards specifically allows the Secretary to modify "performance standards with respect to services required to be provided, including health." § 9836(a)(1)(A). But the Secretary did not rely on this subsection as his statutory authority for the mask and vaccine mandates. Subsection (A) does not appear in the Rule even once. He instead cites subsections (C) ("administrative and financial"), (D) ("facilities"), and (E) ("other") of "program performance standards." 86 Fed. Reg. at 68,052-53 (citing § 9836(a)(1)(C)-(E)). And defendants concede that mask and vaccine mandates are not health services. [Dky. 41] at 40.

Indeed, they are not. Head Start is not providing "health services" to children, nor establishing related "performance standards," by requiring universal masking and staff vaccination. Current performance standards related to health services include examinations and screenings for children. See 45 C.F.R. § 1302.42 (2021). These standards even include assisting children in getting up to date on immunizations. § 1302.42(b)(1).

But these existing regulations differ from the mask and vaccine requirements in three critical ways. One, they do not operate as conditions to participation. The provision of health services, like screenings and immunization assistance, for children already participating in Head Start programs promotes school readiness,

but they are not required. Mandatory vaccines and universal masking, in contrast, present barriers to entry unlike any other “performance standard.” Two, since the first of these regulations were promulgated, the health services offered have always required parental consent. See Program Performance Standards for Operation of Head Start Programs by Grantees and Delegate Agencies, 40 Fed. Reg. 27,562, 27,565 (June 30, 1975) (codified in 45 C.F.R. § 1304.3-3(a)) (requiring “advance parent or guardian authorization” for all screenings and examinations); 45 C.F.R. § 1302.41 (2021) (requiring Head Start programs to “collaborate with parents as partners in the health and well-being of their children” and “[a]t a minimum” to “[o]btain advance authorization from the parent or other person with legal authority for all health and developmental procedures administered through the program”); 45 C.F.R. § 1302.42(b)(ii) (2021) (authorizing Head Start staff to assist parents with scheduling immunizations but saying nothing about enforced masking or vaccinations). And the defendants concede that the Rule at issue is the first time in Head Start’s history that a health procedure was mandated as a prerequisite to participation or employment. [Dkt. #41] at 47. Three, the regulations on which defendants rely only require that immunizations be made available to children; they say nothing regarding staff or volunteers. 45 C.F.R. § 1302.41 (2021) (“Child health status and care”). Here, by contrast, the vaccine and mask mandates condition employment on compliance, and this is the first-ever medical procedure required of Head Start staff under the threat of termination. [Dkt. #41] at 47. These distinctions again highlight why the mandates are not “performance standards” in the first place.

Dkt. #42 at 19–20.

3. The two “primary reasons”

In addition to specifically citing 42 U.S.C. § 9836a(a)(1)(C), (D), and (E), Defendants also claim, “There are two primary reasons that [the Administration for Children and Families] decided to mandate vaccination and mask use.” Appx. 15 (86 Fed. Reg. at 68,066). The first asserted “primary reason” will be discussed in Section B. The second asserted “primary reason” for the vaccine and mask mandate is:

Second, as discussed in this [Interim Final Rule], being fully vaccinated for COVID-19 and using a mask are two of the most effective mitigation strategies available to reduce transmission of COVID-19 [citing Centers for Disease Control and Prevention, “Science Brief: COVID-19 Vaccines and Vaccination,” September 15, 2021]. With this in mind, [the Administration for Children and Families] determined a federal requirement is necessary. While some agencies and localities have implemented vaccine and masking requirements, many have not.

Additionally, vaccine uptake among Head Start staff has not been as robust as hoped for and has been insufficient to protect the health and safety of children and families receiving Head Start services. Combined, these factors leave certain children and families with fewer mitigation strategies in place to protect them than others. It is ACF's responsibility to make sure the environment is as safe as possible for Head Start programs uniformly across all 1,600 grant recipients.

Appx. 15 (86 Fed. Reg. at 68,066).

This second “primary reason” is nothing but a naked assertion that something needs to be done, without any effort to justify the mandate with any statutory authority. That does not justify the Interim Final Rule. To repeat, “Administrative agencies are creatures of statute. They accordingly possess only the authority that Congress has provided.” *NFIB*, 142 S. Ct. at 665. “The challenges posed by a global pandemic do not allow a federal agency to exercise power that Congress has not conferred on it.” *Biden v. Missouri*, 142 S. Ct. at 654. “[O]ur system does not permit agencies to act unlawfully even in pursuit of desirable ends.” *Ala. Ass’n of Realtors v. Dep’t of Health & Human Servs.*, 141 S. Ct. at 2490.

* * *

Defendants’ authority does not extend to exercising powers of vast economic and political significance without limit as it attempts with the Head Start Vaccine Mandate.

42 U.S.C. § 9836a(a)(1)(C), (D), and (E) do not provide statutory authority for the Mandates. Defendants may not adopt the Mandates just because they feel it is “necessary.”

The Interim Final Rule violates the Major Questions Doctrine. It also violates the Administrative Procedure Act because it is “in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.” The Court should “hold unlawful and set aside” the Interim Final Rule. 5 U.S.C. § 706(2)(C).

B. The Interim Final Rule is not simply an extension of preexisting regulations.

The first asserted “primary reason” for the Interim Final Rule is:

First, Head Start programs have a broad set of program performance standards that already include requirements for infection control, exclusion policies, cleaning, sanitizing and disinfecting. The requirement for staying home when sick is part of § 1302.47(b)(4)(i)(A); hand hygiene (handwashing) is included at § 1302.47(b)(6)(i); cleaning, sanitizing, and disinfecting is at § 1302.47(b)(2)(i); and physical distancing is part of § 1302.47(b)(4)(i)(A), which [the Office of Head Start] sees as a strategy for a program’s infection control practices) [sic]. In addition, § 1302.47(b)(1)(iii) states that facilities need to be ‘free from pollutants, hazards and toxins that are accessible to children and could endanger children’s safety,’ though it is difficult be overly prescriptive about ventilation given the range of facilities and spaces used by center-based and family child care programs.

Appx. 15 (86 Fed. Reg. at 68,066) (unmatched right parenthesis in original).

In other words, Defendants are asserting that rules in place before the Interim Final Rule “already include” various requirements, and those various requirements themselves justify the Vaccine Mandate and the Mask Mandate.

Before the Supreme Court issued its opinions about the CMS Mandate and the OSHA Mandate, such an argument carried no weight. In its order granting preliminary relief, the Court did not pay much attention to Defendants’ argument that the Mandates are somehow justified by previously existing regulations.

As the dissent in the CMS case recognized, that changed in January. In upholding the CMS Mandate, “[the Court] asserts that CMS possesses broad vaccine-mandating authority by pointing to a handful of CMS regulations. To begin, the Court does not explain why the bare existence of these regulations is evidence of what Congress empowered the agency to do. Relying on them appears to put the cart before the horse.” *Biden v. Missouri*, 142 S. Ct. 647, 658, 211 L. Ed. 2d 433 (2022) (Thomas, J., dissenting).

The majority agreed with the dissent’s characterization, explaining:

Relying on these authorities [authorizing the Secretary to promulgate, as a condition of a facility's participation in the programs, such "[statutory] requirements as [he] finds necessary in the interest of the health and safety of individuals who are furnished services in the institution,"], the Secretary has established long lists of detailed conditions with which facilities must comply to be eligible to receive Medicare and Medicaid funds [citing various provisions of the Code of Federal Regulations]. Such conditions have **long included** a requirement that certain providers maintain and enforce an "infection prevention and control program designed ... to help prevent the development and transmission of communicable diseases and infections."

Biden v. Missouri, 142 S. Ct. at 650–51 (emphasis added); *see also id.* at 653 ("the Secretary **routinely** imposes conditions of participation that relate to the qualifications and duties of healthcare workers themselves [citing various provisions of the Code of Federal Regulations] ... And the Secretary **has always justified** these sorts of requirements by citing his authorities to protect patient health and safety [citing sections of the C.F.R.]") (emphasis added); 654 (declining to read a statute as prohibiting the CMS Mandate because doing so "would mean that nearly every condition of participation the Secretary has **long insisted upon** is unlawful."), (emphasis added); 654 ("[U]nprecedented circumstances provide no grounds for limiting the exercise of authorities the agency has **long been recognized** to have.") (emphasis added); *see also NFIB*, 142 S. Ct. at 666 ("It is telling that OSHA, in its half century of existence, has never before adopted a broad public health regulation of this kind—addressing a threat that is untethered, in any causal sense, from the workplace. This 'lack of historical precedent,' coupled with the breadth of authority that the Secretary now claims, is a 'telling indication' that the mandate extends beyond the agency's legitimate reach.") (citation omitted).

Thus, the new rule seems to be that if an agency has regulated certain topics for a long time, it may issue new regulations related to the old regulations, without much regard to whether there is any particular statutory authority for the new regulations. On the other hand, when an agency

issues new regulations without any historical precedent, especially public health regulations, the new regulations are probably “beyond the agency’s legitimate reach.”

The Interim Final Rule is the latter kind of new regulation, and Defendants are wrong to suggest otherwise. Head Start does not have a long history of anything close to mandating vaccines and masks. Defendants’ characterizations of the rules relied upon to try to show such a long history do not match the text of those rules.

45 C.F.R. § 1302.47(b)(4)(i)(A) states: “All staff with regular child contact have initial orientation training within three months of hire and ongoing training in all state, local, tribal, federal and program-developed health, safety and child care requirements to ensure the safety of children in their care; including, at a minimum, and as appropriate based on staff roles and ages of children they work with, training in [t]he prevention and control of infectious diseases.” Contrary to Defendants’ assertion, this provision does not include “[t]he requirement for staying home when sick” or “physical distancing.” This is a staff training regulation.

45 C.F.R. § 1302.47(b)(6)(i) specifies: “All staff systematically and routinely implement hygiene practices that at a minimum ensure [a]ppropriate toileting, hand washing, and diapering procedures are followed.” Contrary to Defendants’ assertion, this is not a general “hand hygiene (handwashing)” requirement, but instead refers to cleaning up after urination and defecation.

45 C.F.R. § 1302.47(b)(2)(i) reads: “Indoor and outdoor play equipment, cribs, cots, feeding chairs, strollers, and other equipment used in the care of enrolled children, and as applicable, other equipment and materials meet standards set by the Consumer Product Safety Commission (CPSC) or the American Society for Testing and Materials, International (ASTM). All equipment and materials must at a minimum [b]e clean and safe for children’s use and are appropriately

disinfected.” Contrary to Defendants’ assertion, this provision is not a general “cleaning, sanitizing, and disinfecting” requirement, but only requires that equipment be kept clean.

45 C.F.R. § 1302.47(b)(1)(iii) reads: “All facilities where children are served, including areas for learning, playing, sleeping, toileting, and eating are, at a minimum [f]ree from pollutants, hazards and toxins that are accessible to children and could endanger children’s safety.” Defendants contend that “it is difficult be overly prescriptive about ventilation given the range of facilities and spaces used by center-based and family child care programs.” This comment shows that Defendants understand this requirement to concern “ventilation.” If Defendants are trying to justify the Vaccine and Mask Mandates on a theory that ventilation at Head Start facilities is somehow inadequate, that will not work. This rule requires that ventilation be adequate. It does not allow Head Start facilities to replace inadequate ventilation with vaccine and mask requirements. Thus, contrary to Defendants’ assertion, this rule cannot support the Vaccine and Mask Mandates.

In sum, Defendants’ conclusion that “Head Start programs [already] have a broad set of program performance standards that already include requirements for infection control, exclusion policies, cleaning, sanitizing and disinfecting” is such an exaggeration of its legal authority that it is simply false.

Similarly, Defendants also claim, “The Head Start Program Performance Standards require children to be up to date on immunizations and their state’s Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) schedule (45 CFR 1302.42(b)(1)(i)). When children are behind on immunizations or other care, Head Start programs are required to ensure they get on a

schedule to catch up.” Appx. 8 (86 Fed. Reg. at 68,059). This is false. 45 C.F.R. § 1302.42(b)(1)(i) actually states:

- (1) Within 90 calendar days after the child first attends the program or, for the home-based program option, receives a home visit, with the exceptions noted in paragraph (b)(3) of this section, a program must:
 - (i) Obtain determinations from health care and oral health care professionals as to whether or not the child is up-to-date on a schedule of age appropriate preventive and primary medical and oral health care, based on: The well-child visits and dental periodicity schedules as prescribed by the Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) program of the Medicaid agency of the state in which they operate, immunization recommendations issued by the Centers for Disease Control and Prevention, and any additional recommendations from the local Health Services Advisory Committee that are based on prevalent community health problems;
 - (ii) Assist parents with making arrangements to bring the child up-to-date as quickly as possible; and, if necessary, directly facilitate provision of health services to bring the child up-to-date with parent consent as described in § 1302.41(b)(1).

Thus, Head Start programs are required to find out if children are up to date on “immunization recommendations issued by the Centers for Disease Control” and must “assist parents with making arrangements to bring the child up-to-date as quickly as possible,” ***but only with parental consent.*** This rule does not justify requiring children to wear masks without parental consent.

Moreover, even if existing regulations did already require that children be up to date on vaccinations, that would neither justify the Vaccine Mandate for staff, nor would it justify the Mask Mandate for children, especially for children under five who are too young to be vaccinated. At a

minimum, vaccine and masking requirements for state-run programs are part and parcel with states' authority,³⁸ not the federal government.

Defendants build on this false claim by further asserting, "It is equally important [as the false requirement that children to be up to date on immunizations] that the Head Start program itself is safe for all children, families, and staff. For this reason, the Head Start Program Performance Standards specify that the program must ensure staff do not pose a significant risk of communicable disease (45 CFR 1302.93(a))." In fact, that rule reads,

A program must ensure each staff member has an initial health examination and a periodic re-examination as recommended by their health care provider in accordance with state, tribal, or local requirements, that include screeners or tests for communicable diseases, as appropriate. The program must ensure staff do not, because of communicable diseases, pose a significant risk to the health or safety of others in the program that cannot be eliminated or reduced by reasonable accommodation, in accordance with the Americans with Disabilities Act and section 504 of the Rehabilitation Act.

The rule thus refers to staff that already have a communicable disease that constitutes a disability, not to staff that might temporarily be infected by an airborne virus at some unspecified time in the future. This rule does not allow Head Start to require that its employees get vaccinated. It does not justify the Vaccine Mandate.

42 U.S.C. § 9842(a)–(b) reads:

Each recipient of financial assistance under this subchapter shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such financial assistance, the total cost of the project or undertaking in connection with which such financial assistance is given or used, the amount of that portion of the cost of the project or undertaking supplied by other sources, and such other records as will facilitate an

³⁸ Defendants' own regulations acknowledge this. *See, e.g.*, 45 C.F.R. § 1302.42(b)(1)(i) (referring to the "Medicaid agency of the state in which they operate" and "the local Health Services Advisory Committee").

effective audit. The Secretary ... shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipients that are pertinent to the financial assistance received under this subchapter.

Defendants cite to this as a basis for requiring that Head Start recipients collect and store records relating to the vaccination status of staff and volunteers. However, as seen by the statute's context, these provisions only authorize Defendants to collect information pertinent to auditing the amount and disposition of the financial assistance received by a recipient. This does not authorize the collection of medical records and documentation relating to the vaccination status of staff and volunteers. Whether staff are vaccinated or not is irrelevant to the amount and disposition of financial assistance proceeds received by a recipient.

In short, the Interim Final Rule cannot be justified under *Biden v. Missouri* as “the exercise of authorities that agency has long been recognized to have.” *Biden Missouri*, 142 S. Ct. at 654. It is instead a brand-new assertion of power to issue public health regulations and “extends beyond the agency’s legitimate reach” under *NFIB*. As the Court recognized in its Order granting preliminary relief, “[E]xisting regulations differ from the mask and vaccine requirements in three critical ways.” Dkt. #42 at 19 (cited *infra*).

C. The Interim Final Rule was adopted in violation of various statutory requirements.

1. The Interim Final Rule was adopted in violation of 42 U.S.C. § 9836a(a)(2).

According to the Interim Final Rule, the vaccine mandate and the mask mandate are “program performance standards” under 42 U.S.C. § 9836a(a)(1). As explained above, they are not. But even if they were, 42 U.S.C. § 9836a(a)(2)(A) requires that, in developing program performance standards, the Secretary “shall consult with experts in the fields of child development, early childhood education, child health care, family services (including linguistically and culturally appropriate services to non-English speaking children and their families),

administration, and financial management, and with persons with experience in the operation of Head Start programs.”

According to the Interim Final Rule, Defendants did not do that. Instead, “[t]he Secretary consulted with experts in child health, including pediatricians, a pediatric infectious disease specialist, and the recommendations of the CDC and FDA.” Appx. 3 (86 Fed. Reg. at 68,054).

Moreover, there is no way to evaluate Defendants’ consultations because the agency did not say with whom they met, when they met, for how long, or what they discussed. Plaintiffs have been unable to find any record of the alleged consultations in the administrative record.

The Court has already determined that Plaintiffs have demonstrated a substantial likelihood that Defendants did not comply with 42 U.S.C. § 9836a(a)(2)(A) and that the Rule must therefore be set aside. Dkt. #42 at 25–26.

In addition, 42 U.S.C. § 9836a(a)(2)(B) requires the Secretary to take into consideration ten factors in developing program performance standards. According to the Interim Final Rule, [t]he Secretary considered the Office of Head Start’s past experience with the longstanding health and safety Head Start Program Performance Standards that have sought to protect Head Start staff and participants from communicable and contagious diseases. The Secretary also considered the circumstances and challenges typically facing children and families served by Head Start agencies including the disproportionate effect of COVID-19 on low-income communities served by Head Start agencies and the potential for devastating consequences for children and families of program closures and service interruptions due to SARS-CoV-2 exposures.

Id. None of these factors that Defendants say they considered are factors that they must consider under § 9836a(a)(2)(B).

For instance, § 9836a(a)(2)(B)(vi) requires Defendants to consider “guidelines and standards that promote child health services and physical development, including participation in outdoor activity that supports children’s motor development and overall health and nutrition.” The

Interim Final Rule states, “The Office of Head Start notes that being outdoors with children inherently includes sustained close contact for the purposes of caring for and supervising children.” Appx. 9 (86 Fed. Reg. at 68,060). Thus, children “participat[ing] in outdoor activity that supports children’s motor development” will be required to wear masks. Yet the Interim Final Rule does not discuss how or whether wearing masks during “caring for and supervising children” will affect the beneficial aspects of such activity, in violation of § 9836a(2)(B)(vi).

Subsection (a)(2)(C)(2) requires Defendants to “ensure that [the] revisions in the [program performance] standards will not result in the elimination of or any reduction in quality, scope, or types of health, educational, parental involvement, nutritional, social, or other services required to be provided under such standards as in effect on December 12, 2007.” No such analysis appears in the Interim Final Rule.

Subsection (a)(2)(D) requires Defendants to “consult with Indian tribes, including Alaska Natives, experts in Indian, including Alaska Native, early childhood education and development, linguists, and the National Indian Head Start Directors Association on the review and promulgation of [program performance] standards.” The Interim Final Rule contains a “Tribal Consultation Statement” which states,

[The Administration for Children and Families] conducts an average of five tribal consultations each year for tribes operating Head Start and Early Head Start. The consultations are held in four geographic areas across the country: Southwest, Northwest, Midwest (Northern and Southern), and East. The consultations are often held in conjunction with other tribal meetings or conferences, to ensure the opportunity for most of the 150 tribes that operate Head Start and Early Head Start programs to attend and voice their concerns regarding service delivery. We complete a report after each consultation, and then we compile a final report that summarizes the consultations. We submit the report to the Secretary of Health and Human Services (the Secretary) at the end of the year. We invite public comment on this [Interim Final Rule] if there are concerns specific to Native communities and programs.

Appx. 1 (86 Fed. Reg. at 68,052). In other words, Defendants state only that they meet with Indians once a year. But § 9836a(a)(2)(D) requires consultation with Indians *before* issuing program performance standards, which the Interim Final Rule supposedly contains. It is not enough that Defendants have annual meetings with Indians. Defendants violated 42 U.S.C. § 9836a(a)(2)(D).

Defendants' multiple violations of § 9836a(a)(2) require the Interim Final Rule to be set aside. "The reviewing court shall hold unlawful and set aside agency action, findings, and conclusions found to be without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

2. The Interim Final Rule was adopted in violation of the notice-and-comment requirement.

Defendants must comply with the notice-and-comment requirements of 5 U.S.C. § 553 before promulgating a rule. Subject to certain statutory exceptions not implicated here, a "[g]eneral notice of proposed rulemaking shall be published in the Federal Register." 5 U.S.C. § 553(b). "After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments." 5 U.S.C. § 553(c). "The required publication or service of a substantive rule shall be made not less than 30 days before its effective date [with inapplicable exceptions]." 5 U.S.C. § 553(d).

Notice-and-comment procedures do not apply "when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(3)(B).

The "good cause" exception should be read narrowly and "should not be used to circumvent the notice and comment requirements whenever an agency finds it inconvenient to comply." U.S.

Steel Corp. v. U.S. E.P.A., 595 F.2d 207, 214 (5th Cir. 1979). Likewise, the “public interest” prong only met in “rare circumstances.” *Mack Trucks, Inc. v. E.P.A.*, 682 F.3d 87, 89 (D.C. Cir. 2012).

Defendants acknowledge that the Interim Final Rule is subject to notice-and-comment requirements, but assert that

a combination of factors, including but not limited to failure to achieve sufficiently high levels of vaccination based on voluntary efforts and patchwork requirements, potential harm to children from unvaccinated staff, continuing strain on the health care system, and known efficacy and safety of available vaccines, have persuaded us that a vaccine requirement for Head Start staff, certain contractors, and volunteers is an essential component of the nation’s COVID-19 response. Further, it would endanger the health and safety of staff, children and families, and be contrary to the public interest to delay imposing the vaccine mandate. Therefore, we believe it would be impracticable and contrary to the public interest for us to undertake normal notice and comment procedures and to thereby delay the effective date of this [Interim Final Rule]. We find good cause to waive notice of proposed rulemaking under the APA.

Appx. 8 (86 Fed. Reg. at 68,059). But this is another effort by Defendants to regulate public health generally, which is outside Defendants’ sphere of expertise, just as promulgating general health standards is outside OSHA’s sphere of expertise. *NFIB*, 142 S. Ct. at 665.

In *Biden v. Missouri*, the Supreme Court approved of the promulgation of the CMS Mandate without notice and comment because CMS asserted “that accelerated promulgation of the rule in advance of the winter flu season would significantly reduce COVID-19 infections, hospitalizations, and deaths.” *Biden v. Missouri*, 142 S. Ct. at 654. But unlike the CMS Defendants, who do have expertise in regulating public health, Defendants have no such expertise. *Biden v. Missouri* does not give legal support to Defendants’ failure to engage on notice and comment.

An agency may skip notice and comment for only three reasons. An agency may, for good cause, find (and incorporates the finding and a brief statement of reasons therefor in the rule

issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest. 5 U.S.C. § 808(2). None of those reasons apply here.

“First, an agency may invoke the impracticability of notice and comment.... if, for example, air travel security agencies would be unable to address threats posing a possible imminent hazard to aircraft, persons, and property within the United States, or if a safety investigation shows that a new safety rule must be put in place immediately, or if a rule was of “life-saving importance” to mine workers in the event of a mine explosion. *Mack Trucks*, 682 F.3d at 93 (citations omitted). Defendant cannot show any immediate need to adopt the Interim Final Rule without notice and comment. “Second, an agency may claim notice and comment were ‘unnecessary.’ This prong of the good cause inquiry is ‘confined to those situations in which the administrative rule is a routine determination, insignificant in nature and impact, and inconsequential to the industry and to the public.’” *Id.* at 94. But the Interim Final Rule was no routine determination. “Finally, an agency may invoke the good cause exception if providing notice and comment would be contrary to the public interest.... The question is not whether dispensing with notice and comment would be contrary to the public interest, but whether providing notice and comment would be contrary to the public interest.” *Id.* at 94–95. Presumably, Defendants attempt to rely on this reason to skip notice and comment, but as explained above, they cannot.

The Court has already determined that there is a substantial likelihood that the Interim Final Rule must be set aside for failure to comply with the notice and comment requirement, Dkt. #42 at 26–33, and Plaintiffs adopt the Court’s reasoning.

Defendants' violation of the notice and comment requirement requires the Interim Final Rule to be set aside. "The reviewing court shall hold unlawful and set aside agency action, findings, and conclusions found to be without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

3. The Interim Final Rule is a major rule that was adopted in violation of the Congressional Review Act.

"Before a rule can take effect, the Federal agency promulgating such rule shall submit to each House of the Congress and to the Comptroller General a report containing (i) a copy of the rule; (ii) a concise general statement relating to the rule, including whether it is a major rule; and (iii) the proposed effective date of the rule." 5 U.S.C. § 801(a)(1).

A "major rule" cannot take effect until at least 60 days after Congress receives the report. 5 U.S.C. § 801(a)(3). A "major rule" is a "rule that the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget finds has resulted in or is likely to result in an annual effect on the economy of \$100,000,000 or more." 5 U.S.C. § 804(2).

Defendants acknowledge that "[t]he Office of Information and Regulatory Affairs in the Office of Management and Budget has determined that this action is a major rule because it will have an annual effect on the economy of \$100 million or more." Appx. 12 (86 Fed. Reg. at 68,063).

But Defendants assert that they found

good cause to waive notice of proposed rulemaking under the APA, 5 U.S.C. 552(d), 553(b)(B). For those same reasons [as found to exempt the Interim Final Rule from notice-and-comment under the APA], . . . we find it is impracticable and contrary to the public interest not to waive the delay in effective date of this [Interim Final Rule] under the [Congressional Review Act]. Therefore, we find there is good cause to waive the [Congressional Review Act's] delay in effective date pursuant to 5 U.S.C. § 808(2).

Appx. 8 (86 Fed. Reg. at 68,059).

For the same reasons that good cause does not exist to exempt the Interim Final Rule from notice-and-comment requirements in the APA, good cause does not exist for Defendants to evoke 5 U.S.C. § 808(2).

Defendants' violation of the Congressional Review Act requires the Interim Final Rule to be set aside. "The reviewing court shall hold unlawful and set aside agency action, findings, and conclusions found to be without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

4. The Interim Final Rule was adopted in violation of the Treasury and General Government Appropriations Act of 1999.

Defendants admit that Section 654 of the Treasury and General Government Appropriations Act of 1999 (codified at 5 U.S.C. § 601 note) requires them to determine whether a policy or regulation may negatively affect family well-being. Appx. 11 (86 Fed. Reg. at 68,062).

But they summarily dismiss the need for an impact assessment, reasoning "it is not necessary to prepare a family policymaking assessment ... because [the rule] will not have any impact on the autonomy or integrity of the family as an institution." *Id.*

First, the impact analysis is mandatory. Public Law 105-277, 5 U.S.C. § 601 note ("Before implementing policies and regulations that may affect family well-being, each agency *shall* assess such actions[.]") (emphasis added). Congress specifically required Defendants to include an impact analysis to assess any impact on family well-being. *Id.* Following Defendants' logic used in this Interim Final Rule, Defendants could subjectively determine that the analysis is not required as they see fit to conveniently circumvent the requirement. This directly undermines the statute and renders the impact analysis requirement moot.

Second, an impact analysis has specific requirements that agencies must meet. For example, the impact analysis

must assess such actions with respect to whether—(1) the action strengthens or erodes the stability or safety of the family and, particularly, the marital commitment;(2) the action strengthens or erodes the authority and rights of parents in the education, nurture, and supervision of their children; (3) the action helps the family perform its functions, or substitutes governmental activity for the function; (4) the action increases or decreases disposable income or poverty of families and children; (5) the proposed benefits of the action justify the financial impact on the family; (6) the action may be carried out by State or local government or by the family; and (7) the action establishes an implicit or explicit policy concerning the relationship between the behavior and personal responsibility of youth, and the norms of society.

5 U.S.C. § 601 note. In addition to the other requirements concerning the impact analysis, Defendants wholly and completely ignored this requirement.³⁹

Third, Defendants limit the meaning of “family well-being” in contradiction to the actual text. Assessment of “family well-being” is not defined as an assessment of the impact “on autonomy or integrity of the family as an institution.” Instead, it is an assessment of “family well-being” and requires Defendants to assess the statutorily required factors.

³⁹ See also 5 U.S.C. § 601 note (“(d) Governmentwide family policy coordination and review.--(1) Certification and rationale.--With respect to each proposed policy or regulation that may affect family well-being, the head of each agency shall--(A) submit a written certification to the Director of the Office of Management and Budget and to Congress that such policy or regulation has been assessed in accordance with this section [this note]; and (B) provide an adequate rationale for implementation of each policy or regulation that may negatively affect family well-being. (2) Office of Management and Budget.--The Director of the Office of Management and Budget shall--(A) ensure that policies and regulations proposed by agencies are implemented consistent with this section; and (B) compile, index, and submit annually to the Congress the written certifications received pursuant to paragraph (1)(A). (3) Office of Policy Development.--The Office of Policy Development shall--(A) assess proposed policies and regulations in accordance with this section [this note]; (B) provide evaluations of policies and regulations that may affect family well-being to the Director of the Office of Management and Budget; and (C) advise the President on policy and regulatory actions that may be taken to strengthen the institutions of marriage and family in the United States.”).

Defendants' violation of the Treasury and General Government Appropriations Act of 1999 requires the Interim Final Rule to be set aside. "The reviewing court shall hold unlawful and set aside agency action, findings, and conclusions found to be without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

D. The Interim Final Rule is arbitrary and capricious.

The Interim Final Rule violates the Administrative Procedure Act because it is "arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law," and therefore must be "h[e]ld unlawful and set aside" under 5 U.S.C. § 706(2)(A). "Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

As the Court said in its Order granting preliminary relief:

The Court find that there is a substantial likelihood that the Rule is arbitrary and capricious because it is unreasonably overbroad without a reasonable explanation. It imposes a one-size-fits-all approach with no end date, failing to establish a "rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)). The lack of a reasoned explanation is especially concerning given that the Rule constitutes a drastic change from Head Start's tradition of local flexibility, CDC-reported success in navigating the pandemic through flexibility, and the local programs' reliance interest on that flexibility. See Dkt. No. 39-19 at 1-2.

Dkt. #42 at 33. Plaintiffs could not have said it better themselves and adopt the Court's reasoning.

The Interim Final Rule is arbitrary and capricious for several reasons already identified by the Court. First, it makes "no distinctions in the Rule based on size, location, or transmission rates.

The Head Start Rule’s requirements are universal.... Contrary to this approach, Head Start has a documented history of success from flexible practices depending on local needs.... There is no doubt that Head Start’s traditional local-flexibility approach worked and that the data was before the agency when it nevertheless imposed the one-size-fits-all Rule.” Dkt. #42 at 34–36.

Second, the Interim Final Rule does not have an end date, even though Defendants recognize that the situation in a viral outbreak can and does change. Defendants offered no explanation for its choice of implementing a permanent “Interim” Final Rule. Dkt. #42 at 38.

Additionally, Defendants failed to include evidence contrary to their position in the administrative record. “The whole administrative record ... consists of all documents and materials directly or indirectly considered by agency decision-makers and includes evidence contrary to the agency’s position. The record must include all materials that might have influenced the agency’s decision, not merely those on which the agency relied in its final decision. An agency may not skew the record by excluding unfavorable information but must produce the full record that was before the agency at the time the decision was made.” *Lee Mem’l Hosp. v. Burwell*, 109 F. Supp. 3d 40, 46–47 (D.D.C. 2015) (cleaned up, internal citations and quotation marks omitted).

The administrative record does not contain any evidence contrary to Defendants’ position. For instance, the World Health Organization (WHO) and the United Nations Children’s Fund (UNICEF) specifically advised that “Based on the expert opinion gathered through online meeting and consultative processes, children aged up to five years should not wear masks.”⁴⁰

⁴⁰ *Advice on the use of masks for children in the community in the context of COVID-19*, WORLD HEALTH ORGANIZATION, (Aug. 21, 2020), chrome-extension://efaidnbmnnibpcajpcglclefindmkaj/viewer.html?pdfurl=https%3A%2F%2Fapps.who.

For these reasons, the Interim Final Rule violates the Administrative Procedure Act because it is “arbitrary and capricious, and abuse of discretion, or otherwise not in accordance with law,” and therefore must be “held unlawful and set aside under 5 U.S.C. § 706(2)(D).

E. The Interim Final Rule is an unconstitutional exercise of the Spending Power.

If 42 U.S.C. § 9836a(a)(1) authorized Defendants to enforce the Vaccine Mandate and the Mask Mandate, which it does not, then it would be an unconstitutional condition on the receipt of federal funds.

“[I]f Congress intends to impose a condition on the grant of federal moneys, it must do so unambiguously,” so “States [can] exercise their choice knowingly.” *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981). The executive branch cannot impose conditions on spending that the Constitution would prohibit it from imposing directly, because that authority belongs to Congress. *See id.* at 17. Only Congress can condition the receipt of federal funds.

42 U.S.C. § 9836a(a)(1) does not authorize, let alone unambiguously impose, the Vaccine Mandate or the Mask Mandate. And there is no nexus between grants to Head Start and vaccine and mask requirements. *South Dakota v. Dole*, 483 U.S. 203 (1987). Thus, the Vaccine Mandate and the Mask Mandate are not authorized under the Spending Clause.

Additionally, Defendants incorrectly claim:

[T]his [Interim Final Rule] preempts the applicability of any State or local law providing for exemptions to the extent such law provides broader grounds for exemptions than provided for by Federal law and are inconsistent with this IFC. In these cases, consistent with the Supremacy Clause of the Constitution, the agency intends that this rule preempts State and local laws to the extent the State and local laws conflict with this rule.

int%2Firis%2Fbitstream%2Fhandle%2F10665%2F333919%2FWHO-2019-nCoV-IPC_Masks-Children-2020.1-eng.pdf%3Fsequence%3D1%26isAllowed%3Dy&clen=304051&chunk=true (last visited April 13, 2022).

Appx. 12 (86 Fed. Reg. at 68,063). But Congress may not preempt State law through the Spending Clause. Instead, “in exercising its spending power, Congress may offer funds to the States, and may condition those offers on compliance with specified conditions. These offers may well induce the States to adopt policies that the Federal Government itself could not impose.” *Nat’l Fed’n of Indep. Bus. v. Sebelius* (“Obamacare”), 567 U.S. 519, 537 (2012). A valid exercise of the Spending Power—which the Interim Final Rule is not—can only induce States to change their own laws. It does not preempt State law. The only remedy for States which do not change laws that conflict with the conditions is that they do not get the funding. “[O]ur cases have recognized limits on Congress’s power under the Spending Clause to secure state compliance with federal objectives. We have repeatedly characterized Spending Clause legislation as much in the nature of a contract.” *Obamacare*, 567 U.S. at 576–77 (cleaned up). “Congress may attach appropriate conditions to federal taxing and spending programs to preserve its control over the use of federal funds. In the typical case we look to the States to defend their prerogatives by adopting the simple expedient of not yielding to federal blandishments when they do not want to embrace the federal policies as their own.” *Obamacare*, 567 U.S. at 579.

The Interim Final Rule exceeds the powers granted to the federal government under the Spending Clause, and does not preempt Texas law. The Court should enjoin enforcement of this unconstitutional Interim Final Rule.

F. The Interim Final Rule violates the Anti-Commandeering Doctrine.

“[T]he Federal Government may not compel the States to implement, by legislation or executive action, federal regulatory programs.” *Printz v. United States*, 521 U.S. 898, 925 (1997).

Even if the Vaccine Mandate and the Mask Mandate were valid, which they are not, they would unconstitutionally compel LISD and others, such as Texas Tech, to administer a federal

regulatory program by forcing them to either fire their unvaccinated employees—and fire and expel staff and children who do not wear mask—or risk their Head Start funding.

Forcing Head Start programs to comply with the Vaccine Mandate and the Mask Mandate under threat of the loss of all funding is unconstitutionally coercive; it is a gun to the head that compels Texas and other governmental entities such as LISD operating Head Start programs to participate against their will. *See Obamacare*, 567 U.S. at 580.

For all these reasons, the Interim Final Rule was adopted pursuant to an unconstitutional exercise of authority. The Court should enjoin enforcement of this unconstitutional Interim Final Rule.

G. The Interim Final Rule violates the Tenth Amendment.

The structure of the U.S. Constitution and the text of the Tenth Amendment protect federalism. The powers not delegated by the Constitution to the federal government are reserved to the States. Through the Vaccine Mandate and the Mask Mandate, the federal government seeks to exercise power far beyond what was delegated to the federal government under the United States Constitution. The power to impose vaccine mandates and mask mandates, to the extent that any such power exists, is a power reserved to the States.

“[T]he police power of a state” includes, above all, the authority to adopt regulations seeking to “protect the public health,” including the topic of mandatory vaccination. *Jacobson v. Massachusetts*, 197 U.S. 11, 24–25 (1905). These matters “do not ordinarily concern the national government.” *Id.* at 38.

By interfering with the traditional balance of power between the States and the federal government, Defendants violated the Tenth Amendment and structural principles of federalism. The Court recognized this in its Order granting preliminary relief. While States may require

vaccination as a function of its authority to regulate health and safety, here Defendants' vaccine mandate stems from a federal agency. To exercise such wide-sweeping authority in an area traditionally reserved to the States, Defendants must point to "exceedingly clear" Congressional language demonstrating a fundamental change in the balance of power between the Federal government and the States. *U.S. Forest Serv. v. Cowpasture River Pres. Ass'n*, 140 S. Ct. 1837, 1850 (2020) (citing *Gregory v. Ashcroft*, 501 U.S. 452, 460 (1991)). No such language exists.

Accordingly, the Interim Final Rule violates the Tenth Amendment. The Court should enjoin enforcement of this unconstitutional Interim Final Rule.

CONCLUSION

Plaintiffs request that the Court grant their Motion for Summary Judgment and enter a judgment holding the Interim Final Rule unlawful and setting it aside under the Administrative Procedure Act because

- It violates the Major Questions Doctrine.
- It exceeds statutory authority under 5 U.S.C. § 706(2)(C).
- It is not an exercise of authority that Defendants have long been recognized to have under *Biden v. Missouri*.
- It was adopted in violation of the Head Start Act itself, 42 U.S.C. § 9836a(a)(2).
- It was adopted in violation of the notice-and-comment requirement.
- It was adopted in violation of the Congressional Review Act.
- It was adopted in violation of the Treasury and General Appropriations Act of 1999.

Plaintiffs further request that the Court enjoin enforcement of and find that the Interim Final Rule because it violates the Constitution in the following ways:

- It is an unconstitutional exercise of the Spending Power.
- It violates the Anti-Commandeering Principle.
- It violates the Tenth Amendment.

Respectfully submitted,

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CERTIFICATE OF SERVICE

We certify that a true and accurate copy of the foregoing document was filed electronically (via CM/ECF) on April 13, 2022.

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